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SHORT REPORT

AngioSeal Device Malfunction: A Case Report of Dilator Tip Fracture and Successful Endovascular Retrieval

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Abstract In this case report we describe an unusual case of AngioSeal (St. Jude Medical, MN) device malfunction where the arteriotomy locator tip broke off during the AngioSeal deployment. This case report highlights a previously unreported complication of an AngioSeal and we propose some modifications of AngioSeal device and other measures to prevent this from reoccurring. We also describe the endovascular technique that could be used to retrieve a retained tip of the arteriotomy locator using a snare.

Introduction

Vascular closure devices (VCD) are being increasingly used for vascular closure and hemostasis after percutaneous endovascular therapies. Studies have shown that closure devices may reduce hemostasis time and facilitate early ambulation, potentially decreasing hospital length of stay and improving patient satisfaction.[1] AngioSeal is the most commonly used VCD, which is a bio-absorbable, sheath-delivered device that deposits a small collagen plug into the puncture channel to seal the puncture defect mechanically. However, AngioSeal deployment can be associated with various complications. We describe an unusual complication of an AngioSeal device malfunction which has not been reported.

Case Report

We report here a 72 year old male with body mass index of 42 kg/m^2 who had a previous history of coronary artery disease, and drug eluting stent implantation in the left anterior descending artery and left circumflex arteries. He was seen in our outpatient cardiology clinic for evaluation of new exertional angina. The patient underwent cardiac catheterization, which revealed an ostial right coronary artery occlusion. The patient had a large panniculus, and was found to have considerable scarring in the right groin region from previous cardiac catheterizations, causing

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considerable difficulty advancing a vascular sheath into the common femoral artery. He also had a very tortuous abdominal aorta, which caused significant difficulty in engagement of the right coronary artery. We attempted to recanalize the chronically occluded RCA, but the procedure was aborted due to poor guide catheter engagement. We decided to use a 6F AngioSeal (St.Jude Medical, MN) as a closure device for femoral artery access site, partly due to the prior difficulty with sheath insertion. The AngioSeal insertion sheath and the arteriotomy locator were advanced over the guidewire into the femoral artery by standard technique that involved advancing the sheath while rotating the sheath and arteriotomy locator. This was also difficult due to the scarring at the artery access site, complicated by the depth of the artery, which allowed some amount of buckling of the sheath/arteriotomy locator combination between skin and artery. After some effort, the sheath/arteriotomy locator assembly was successfully advanced into the artery, with good pulsatile flow exiting the arteriotomy locator port. The arteriotomy locator was withdrawn, leaving the guidewire in place (which has become our practice, affording a final chance to ensure the sheath tip remained in an intravascular position). Upon removal of the arteriotomy locator of the AngioSeal delivery system, we immediately noted that the tip of the arteriotomy locator was missing, having broken off at the site of the arteriotomy locator holes. At that point we still had the guidewire inside the femoral artery within the AngioSeal sheath. After reviewing various options, and consulting with our vascular surgeon, we elected to use a snare (Goose Neck snare kit 7 mm $\times$ 200 cm) to retrieve the tip of the arteriotomy locator, presuming that tip was still on the guidewire. As we advanced the snare through the sheath alongside the guidewire, there was resistance, and the tip was felt to be within the distal portion of the sheath.

The snare was removed and the insertion sheath was pulled out, again leaving the guidewire in place, with a hope of retrieving the tip of the arteriotomy locator with it; unfortunately the tip remained in the patient and did not come out with the sheath. A new standard vascular sheath was placed (6F Cordis) over the wire, pushing the retained fragment of the arteriotomy locator forward, though this was not visible on fluoroscopy. Angiography of the femoral artery through the sideport of the Cordis sheath confirmed that the fractured dilator tip was retained on the wire by revealing that there was a filling defect around the guide wire. A snare was then advanced with the snare looped over the wire, was negotiated over the tip of arteriotomy locator, where it was clinched tightly about the wire above the retained radiolucent arteriotomy locator tip, confirmed by repeat femoral angiography (Fig. 3). The snared guidewire and fractured arteriotomy locator tip were withdrawn to the Cordis sheath, but would not enter the distal end of the sheath. The tip was then pulled out with gentle traction along with the Cordis sheath and snare, with enough length of guidewire left in the artery to maintain access (Fig. 2). Fig. 1 shows the picture of the arteriotomy locator tip that was retrieved. The vessel was then sealed using an 8F AngioSeal, after exchanging for a super-stiff Amplatz wire to prevent excessive buckling of that device during insertion through the soft tissue between the skin entry site and the arteriotomy.

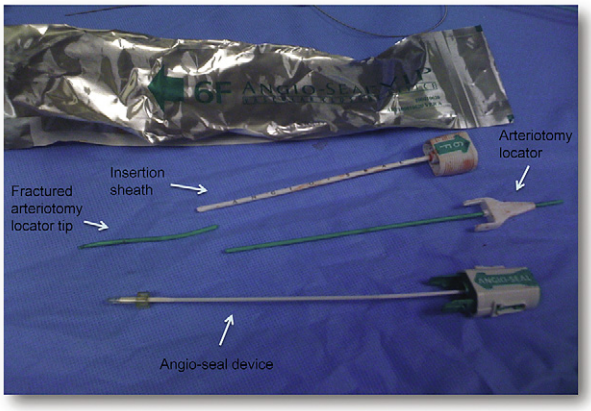

Figure 1 Photograph of the AngioSeal device kit with the fractured arteriotomy locator tip after it was retrieved from the patient.

Discussion

Various complications of vascular closure devices have been described including retroperitoneal bleeding, hematoma/hemorrhage requiring blood transfusion, or surgical intervention, pseudo-aneurysm formation necessitating thrombin injection or surgical repair, malfunction of VCD causing stenosis, occlusion or peripheral vascular embolization leading to lower limb ischemia/claudication requiring surgical interventions, device failure (failure to deploy a sealant/collagen plug), hematoma >5 cm and arterio-venous fistula not requiring surgical treatment.[2–5] Nikolsky et al. have described in their meta-analysis study that the incidence of the AngioSeal related complications is up to 2.5% and the risk of those complications was similar with manual compression.[6]

To the best of our knowledge, this is the first case report where the tip of an AngioSeal arteriotomy locator broke off during deployment. It is our feeling that thorough knowledge of how a device works, including possible mechanisms of failure, can ensure the best application of that device.

This case also highlights several important features of the AngioSeal device. The arteriotomy locator tip is not

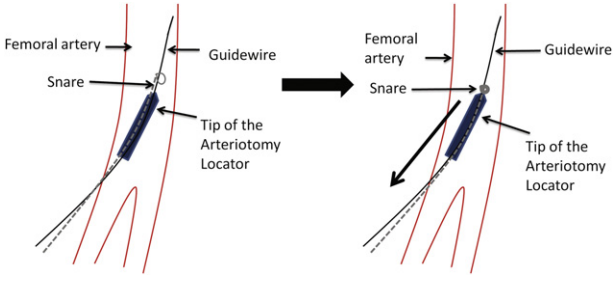

Figure 2 Sketch showing the method of fractured arteriotomy locator tip retrieval with the help of a snare. The loop of the snare was passed beyond the fractured tip of arteriotomy locator on the guidewire (left diagram) and then pulled (direction of the arrow in the right diagram).

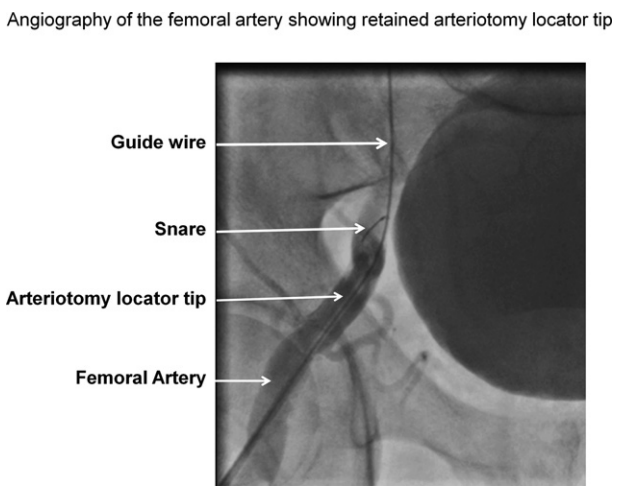

Figure 3 Fluoroscopic image of the Femoral artery showing the snare passed beyond the fractured tip of the arteriotomy locator on the guidewire. The fractured arteriotomy locator tip can be seen as a filling defect on the guidewire.

radio-opaque, and the lack of radio-opacity led to uncertainty in locating the fractured tip of the device. The location of the device was the key to the management strategy for retrieving the tip of the arteriotomy locator. Had the device embolized into the distal lower extremity, which would have been extremely likely had we pulled the guidewire completely out along with the arteriotomy locator (as the instructions for use suggest), it would have been near impossible to locate using fluoroscopy, and would potentially have confounded any attempts at Fogarty embolectomy or other retrieval techniques.

The arteriotomy locator fractured at the site of the two side holes in the middle of the body, which reveals a potential weak area on the dilator, and any manipulation of this "weak link" could predispose to a fracture. The device could be made safer and less vulnerable to fracture by the use of a different polymer or perhaps drilling the locator hole through only one side rather than through and through. Alternatively in patients with significant scarring, AngioSeal should be avoided or other puncture site e.g., left femoral artery should be chosen if planning to use an AngioSeal device.

Conclusion

This case report highlights a previously unreported potential complication of an AngioSeal, leading to suggestions for possible modifications of the device that might limit or eliminate the potential for this occurring again, or if it did occur, for minimizing the potential harmful consequences to the patient. These are: using a radio-opaque material in the dilator especially at the arteriotomy locator tip, strengthening the arteriotomy locator in the region of the side holes. In addition we also describe the endovascular technique that could be used to retrieve a retained tip of the arteriotomy locator using a snare. This also demonstrates that our practice of leaving the guidewire in the patient for a few seconds after removal of the dilator not only gave us the assurance that the sheath tip was in an intra-arterial location, but also made possible the successful retrieval of the fractured tip, as it prevented distal embolization and thus a major morbid consequence.

Disclosure Statement

The authors report no financial relationships or conflicts of interest regarding the content herein.

Ethical Approval

None.

Conflict of Interest/Funding

None.

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